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Commissioner for F

Office of Regulatory Policy Food and Drug Administration 10903 New Hampshire Ave., Bldg. 51, Rm. 6222 Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached documents were submitted in accordance with 37 C.F.R. § 1.765 on December 11, 2008 and relate to the application for patent term extension of U.S. Patent No. 5,451,233. The patent term extension application for U.S. Patent No. 5,451,233 was filed on July 25, 2008, under 35 U.S.C. § 156 and previously transmitted to FDA on July 30, 2008.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till

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cc:

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